EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
MDL No. 2326

IN RE: BOSTON SCIENTIFIC CORP.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION
THIS DOCUMENT RELATES TO:
ALL WAVE 4 IN MDL NO. 2326

VIDEOTAPED DEPOSITION OF BRUCE A. ROSENZWEIG, M.D.

Chicago, Illinois
Thursday, August 30, 2018

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The videotaped deposition of BRUCE A. ROSENZWEIG, M.D., taken pursuant to the Federal Rules of Civil Procedure of the United States District Courts pertaining to the taking of depositions, taken before Marianne Nee, a Certified Shorthand Reporter of the State of Illinois, CSR License No. 084-002341, taken at 161 North Clark Street, Suite 3050, Chicago, Illinois, on Thursday, August 30, 2018, commencing at 9:04 a.m.

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T A B L E O F C O N T E N T S

E X H I B I T S

* * *

P R O C E E D I N G S:

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(Exhibit 1 was marked for identification.)

(Exhibit 2 was marked for identification.)

(Exhibit 3 was marked for identification.)

(Exhibit 4 was marked for identification.)

(Exhibit 5 was marked for identification.)

THE VIDEOGRAPHER: We are now on the record. My name is Anthony Micheletto. I'm the videographer with Golkow Litigation Services.

Today's date is August 30, 2018. The time is 9:04 a.m. as indicated on the video screen. This video deposition is being held in Chicago, Illinois in the matter of In Re: Boston Scientific Corporation, Pelvic Repair System, Product Liabilities Litigation in the United States District Court in the Southern District of West Virginia, Charleston Division.

Our deponent is Bruce Rosenzweig, M.D.

Will counsel please identify yourselves for the video record?

MS. HUTSON: My name is Shelley Hutson from Clark Love & Hutson. I represent the plaintiff in the Boston Scientific MDL.

Are you going to introduce yourself for the record, Jim? You probably ought to.

MR. PERDUE: I guess, with the permission of counsel. There won't be two at a time, I can promise you that. Jim Perdue, also for the plaintiffs in the MDL.

MR. MOLL: Ken Moll from Moll Law Group, representing various plaintiffs.

MS. STEELE: Andrea Steele, Shook Hardy & Bacon, representing the defendant Boston Scientific.

THE VIDEOGRAPHER: Our court reporter today is Marianne Nee. Please swear in the doctor.

(Witness sworn.)

BRUCE A. ROSENZWEIG, M.D.,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MS. STEELE:

Q. Good morning, Dr. Rosenzweig.

A. Yes, ma'am.

Q. How are you this morning?

A. Fine. Thank you. And yourself?

Q. Good. Can you state your full name for the record, please?

A. Bruce Allen Rosenzweig.

Q. And can you state your current business address for the record?

A. 1725 West Harrison Street, Suite 358 here in Chicago.

Q. And you've given various depositions in the past, so you're familiar with how this will go today; is that right?

A. Yes, ma'am.

Q. And probably most importantly, if at any time I use a scientific or medical term incorrectly or my question is not understood, please let me know and I'll rephrase my question. Okay?

A. Yes.

Q. And what did you do to prepare for your

deposition?

A. I reviewed my general causation report that was filed June 4, 2018. I reviewed some literature, some of my older reports and testimonies.

Q. And what literature did you review?

A. Literature that is cited in my report and also other literature that is part of my reliance list.

Q. Did you conduct any additional literature searches before your deposition?

A. No, ma'am.

Q. Did you review any literature that's not either cited in the body of your report or in the reliance list attached to your report?

A. Not that I specifically recall.

Q. Were there certain categories of literature you wanted to review before your deposition?

A. No.

Q. And it's your understanding that this deposition will just cover your general causation opinions offered in your June 2018 report?

A. Correct.

Q. Today we won't be covering the case-specific opinions you've offered regarding various plaintiffs in the Boston Scientific MDL.

A. Correct.

Q. And do you recall what prior testimony you reviewed before your deposition today?

A. Not that I specifically recall but, as you know, I gave general causation testimony on the Obtryx in the consolidated trial in West Virginia. I gave a general causation deposition on Advantage, Advantage Fit and Lynx. If I remember correctly, that was November of 2014.

I also gave a general causation deposition on Solyx and then trial testimony on Solyx, and then recently, last year in September I gave general causation testimony on the Lynx device in state court in Delaware.

Q. Thank you. Did you perform any research using the FDA MAUDE database in preparation?

A. No.

Q. Did you review any Boston Scientific internal documents or labeling?

A. I probably looked at the Instructions For Use for the various devices we're going to discuss today.

Q. Did you speak with anyone in preparation for your deposition?

A. Yes.

Q. Who did you speak with?

A. Ms. Hutson and Mr. Perdue.

Q. And for approximately how long did you meet?

A. Four or five hours.

Q. Have -- since your last general cause deposition, have you given -- have you spoken with any other retained experts for plaintiffs in the Boston Scientific litigation?

A. And which general causation deposition are you talking about?

Q. Since your last one in the MDL, so approximately late 2014.

A. And which again are you talking about, the Solyx or the Advantage?

Q. Regarding the Advantage.

A. No.

Q. Have you spoken with any retained

experts regarding Solyx?
A. No.
Q. Just generally in the last two to three years have you spoken regarding your opinions with any other retained experts for plaintiffs?
A. No.
Q. So you haven't discussed any testing to be conducted with other experts?
A. No. I make it a point not to talk to the other experts in the MDL.
Q. I'm going to hand you what's been marked as Exhibit 1 to your deposition.
A. Yes.
Q. And do you recognize Exhibit 1?
A. Yes.
Q. And this is the notice of deposition, and if you turn to the second page, Exhibit A --
A. Yes.
Q. -- did you bring any documents responsive to this notice with you today?
A. I brought a copy of my report. The testimony history and my CV are up to date as of when it was filed on the 4th of June 2018.
Q. Did you bring any invoices with you

today?

A. No, I did not. I do not keep invoices, but I'm sure Ms. Hutson would make those available.

MS. STEELE: We just request you make those available.

MS. HUTSON: And we will.

BY MS. STEELE:

Q. And the copy of your expert report that you brought with you today, does it contain any notes or markings?

A. It just has highlights to allow me to quickly and expeditiously get to portions of my report to help make things run smoothly today.

Q. And I'll mark that as Exhibit 6 to your deposition.

A. Yes. You mean my report?

Q. The report that you brought with you today.

A. Excellent.

(Exhibit 6 was marked for identification.)

BY MS. STEELE:

Q. And you can keep it with you.

A. Thank you.
Q. Is Exhibit 2 I previously marked a clean copy of your expert report --
A. Yes, ma'am.
Q. -- filed on June 4, 2018?
A. Yes, ma'am.
Q. I'll hand you Exhibit 3 which is Exhibit A which is -- if you can identify what Exhibit A is for the record.
A. This is my curriculum vitae.
Q. And that is current?
A. Yes. I haven't updated it in a few years. There is nothing much to update.
Q. And I'll hand you what's been previously marked as Rosenzweig Exhibit 4 which is Exhibit B attached to your expert report.
A. Yes.
Q. And can you identify what Exhibit 4 which is Exhibit B to your report is?
A. This is my testimony history.
Q. And that is up to date as of June 2018?
A. Actually I think there is just one Boston deposition that I thought was done before that, but it must have been done after that and

that was a case-specific deposition, Ferraro or Fajardo.

Q. Fardo?

A. No. Fajardo. It is the one that the trial is next week in Connecticut.

Q. And are you scheduled to go to Connecticut next week?

A. Yes, ma'am.

Q. Which day?

A. I think Wednesday. Are you going to be there, too?

Q. We'll see.

A. Unless you guys decide to settle over the weekend, make everybody's life easier.

Q. That's above most of our pay grades.

And I'm going to hand you what has been previously marked as Exhibit 5 which is Exhibit C to your expert report.

A. Yes.

Q. And can you identify what Exhibit 5 is?

A. This is a reliance list of the literature and internal documents that I've reviewed.

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(Exhibit 7 was marked for identification.)

BY MS. STEELE:

Q. I'll mark as Exhibit 7 and hand you what has been marked as Exhibit 7. And is that a copy of your previous general causation report in Wave 1 and 2 regarding Advantage, Advantage Fit and Lynx?

A. Correct.

Q. And have any of the opinions expressed in Exhibit 7 changed since 2014 or have they only been supplemented?

A. They have only been supplemented. Again, what I try to do with this report since -- in anticipation of one of your future questions, yes, I do stand by all my prior testimony that I've given in my general causation opinions, both for the Obtryx, the Solyx, the Advantage, the Advantage Fit, and the Lynx.

Q. I want to talk about how you went about preparing your supplemental report that was marked as Exhibit 2 from Exhibit 7 and various other general reports that you filed before.

When were you first asked to update your report for Wave 4?

A. The spring of 2018.

Q. And what steps did you undergo to update your report?

A. Add specific information about the Solyx, the Obtryx and the Prefyx and the Pinnacle and Uphold to the basics of the report that was already filed for Advantage, Advantage Fit and Lynx.

Q. Your expert report from June 2018 does not contain any specific opinions regarding the Uphold Lite product; is that correct?

A. Correct.

Q. Your expert report served in June 2018 does not contain any expert opinions regarding the Boston Scientific Upsylon product, correct?

A. Correct.

Q. Your expert report served in June of 2018 does not contain any specific opinions regarding Polyform sheet mesh, correct?

A. Correct.

Q. In preparing your June 2018 expert report, were you given additional materials to

review from plaintiffs' counsel?

A. Not that I specifically recall.

Q. And I think one of the main additions to your report is commentary on deposition testimony given by Janice Connor in 2015?

A. That -- probably, yeah. Let me just check the date. Yes.

Q. And had you reviewed that prior to updating your report or did you review it in the course of updating your 2018 report?

A. No. I had reviewed it prior to.

Q. Did you conduct any additional literature searches?

A. Specifically for this?

Q. Specifically to update this report.

A. No.

Q. This is the first report that you've authored with general opinions regarding the Uphold and Pinnacle devices; is that correct?

A. Correct.

Q. Did you conduct literature searches regarding Uphold and Pinnacle?

A. Specifically for this report, no. I had done that prior.

Q. Are you currently in private practice?
A. Yes, ma'am.
Q. And is that the same private practice you've operated for the last 15, 20 years?
A. About 15 years, actually 16 years, yes.
Q. How many employees do you have?
A. I have three employees right now.
Q. Who are the three employees and what are their roles?
A. One is my nurse, one is my secretary, and one is my wife who runs her own weight loss clinic.
Q. How many days a week do you currently perform surgery?
A. A day and a half a week.
Q. When is the last time you performed surgery?
A. Well, I've been out on family medical leave for the last month. As you know, this deposition was scheduled earlier in the month. My wife had surgery, so I've been taking time, since she can't really do very much with her arm being in a sling, but I did a minor case two weeks ago. Before that it was in August, July.

Q. How many days a week do you see patients in the office?

A. Two days a week.

Q. How often do you remove polypropylene mesh products?

A. The last one I did was a Boston Scientific Advantage and that was in July. It was a retropubic removal, so I think I've done maybe four or five this year.

Q. In 2018 you performed four to five mesh removals in total?

A. Correct.

Q. And for the one that you performed in July that was a Boston Scientific Advantage product, how did you know that it was a Boston Scientific Advantage?

A. I had her prior medical records.

Q. Was it a complete sling removal or just a partial excision?

A. She had two prior vaginal removals, and so we went in to take out the rest through a retropubic removal. So as best I could, it was a complete removal.

I don't think in many instances or the

majority of instances you can ever get out all the mesh, particularly when it comes out piecemeal.

Q. For your treatment of patients with stress urinary incontinence, is the laparoscopic Burch still your primary procedure?

A. I have never testified that the laparoscopic Burch is my primary procedure.

Q. Is open Burch your primary procedure?

A. Correct.

Q. Are there any circumstances under which a polypropylene midurethral sling would be appropriate to implant into a patient with stress urinary incontinence?

A. I do not implant polypropylene midurethral slings for stress urinary incontinence.

Q. Would you refer a patient, if appropriate, for placement of a polypropylene midurethral sling to treat her stress urinary incontinence?

A. If a patient wants a polypropylene midurethral sling to treat her stress urinary incontinence and I've discussed with them the

risks and benefits, I would refer that patient off to a physician to place a polypropylene midurethral sling.

Q. Who would you refer her to?

A. There is a urogynecologist at Rush. There are urologists, urogynecologists at Rush who would implant a polypropylene midurethral sling in the appropriate patient.

Q. Do you know what manufacturers of polypropylene midurethral slings are currently being implanted at Rush?

A. If I recall, we only have Ethicon products.

Q. Do you discuss the option of a polypropylene midurethral sling with all of your patients who are seeking surgical treatment for stress urinary incontinence?

A. I discuss that as a treatment option. I discuss with them the risks and benefits. I discuss with them why I don't use polypropylene midurethral slings because of the risks far outweighing the benefits. I discuss with them, as I discussed in my report, that polypropylene is an inappropriate material to place in a

woman's pelvis for all the reasons that I've stated in my general causation report.

Q. Have you made any efforts to stop the implantation of polypropylene midurethral slings at Rush Hospital?

A. I do not implant midurethral slings, polypropylene midurethral slings, so in my practice, yes.

Q. Have you made any efforts in the practices of your colleagues at Rush to stop the implantation of polypropylene midurethral slings?

A. I discuss the risks of polypropylene placed in the female pelvis as a treatment for stress urinary incontinence with the doctors that I work with, residents, fellows, and I have not petitioned to have midurethral slings removed. I just discuss my opinions about and the facts about polypropylene products, one of them is to treat stress urinary incontinence, with my colleagues at Rush.

Q. Is it reasonable for your colleagues at Rush to implant polypropylene midurethral slings?

A. It is not outside the standard of care. However, as more data is being discussed and documented in the medical literature, I find that more physicians have become less likely to implant polypropylene midurethral slings in patients.

Q. And what is that impression based on?

A. Well, No. 1, if you look at the country of Scotland has banned polypropylene products. England has a one-year hold on midurethral slings. Australia and New Zealand has banned -- New Zealand has banned polypropylene products. New Zealand, there are certain polypropylene products that are no longer available.

Q. In the United States the use of polypropylene midurethral slings has not been banned, correct?

A. Correct.

Q. All of the major medical societies for the fields of urology, gynecology and urogynecology continue to support the use of polypropylene midurethral slings in appropriate patients, correct?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. As of the last position statements that I saw, but again, I would disagree that it is the worldwide gold standard because of the testimony I just gave about where polypropylene midurethral slings are no longer available.

Therefore, it can't be a worldwide gold standard if it's not available worldwide.

BY MS. STEELE:

Q. I want to transition to the use of polypropylene mesh transvaginally for the treatment of pelvic organ prolapse.

A. Okay.

Q. Do surgeons at Rush currently implant polypropylene mesh transvaginally for the treatment of pelvic organ prolapse?

A. Are you talking about kits or as an inlay?

Q. Either.

A. I'm not aware that we have polypropylene kits, armed polypropylene kits or unarmed polypropylene kits for the treatment of pelvic organ prolapse at Rush.

Q. Are surgeons at Rush currently

implanting polypropylene sheet mesh that is cut by the surgeon for the treatment of pelvic organ prolapse transvaginally?

MS. HUTSON: Object to form.

BY THE WITNESS:

A. Not that I'm aware of.

BY MS. STEELE:

Q. Are surgeons at Rush currently implanting polypropylene mesh abdominally for the treatment of pelvic organ prolapse?

A. As an abdominal colposacropexy, I do think that there are physicians that are using polypropylene mesh in a sheath format to be used to treat pelvic organ prolapses and abdominal colposacropexy.

Q. Do you know what manufacturer's sheet mesh is being used?

A. Not that I specifically recall.

Q. Will polypropylene mesh that is implanted via an abdominal sacrocolpopexy degrade in the female pelvis?

A. Yes.

Q. Will polypropylene mesh that is implanted via an abdominal sacrocolpopexy shrink

or contract in the female pelvis?

A. Yes.

Q. Have -- and you do not currently implant polypropylene mesh in the female pelvis for any indication or via any route; is that correct?

A. Correct. In fact, I don't use polypropylene suture.

Q. Is the use of transvaginal mesh, whether in a sheet mesh or in a kit for the treatment of pelvic organ prolapse, outside the standard of care?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Currently, because there are 522 studies going on to look at the safety and efficacy of polypropylene kits in the treatment of pelvic organ prolapse and because of the recent FDA up-classing of the polypropylene kits in the treatment of pelvic organ prolapse to a Class III device, it is my opinion that the use of it should be considered experimental and that patients, if it is going to be used in them, should be warned that this is an experimental

product.

It should be used with that understanding, that the safety and efficacy has not been determined for the kits that are currently still being used and being evaluated under 522 studies. It's my understanding that those 522 studies have not been completed and, therefore, the data is not available and, therefore, the safety and efficacy has not been confirmed.

Q. Is a surgery or device that is considered experimental outside the standard of care?

MS. HUTSON: Object to form.

BY THE WITNESS:

A. If the patient understands that this is -- the safety and efficacy of this device has not been documented, that it is currently being studied under a 522 protocol by the FDA, has currently been up-classed from a Class II device to a Class III device, and the patient understands all of that and it's being used as an experimental device, then it would be not inappropriate to use that device.

BY MS. STEELE:

Q. And is that opinion true from the time that the 522s were ordered?

A. Well, yes. I mean, that's why the 522s were ordered is the FDA determined that the safety and effectiveness of pelvic floor prolapse devices, that the kits had not been determined and, therefore, required any manufacturer that wanted to continue to sell their device to do 522 studies to prove the safety and effectiveness.

In the meantime it was then up-classed to a Class III device and many of the devices had been withdrawn from the market because the manufacturers did not want to do 522 studies. So obviously there is a significant degree of concern over the safety and efficacy of these products.

Q. Boston Scientific continues to market a transvaginal mesh kit for the treatment of pelvic organ prolapse, correct?

A. Correct, Uphold Lite.

Q. Boston Scientific did choose to conduct a 522 study on the Uphold Lite, right?

A. Correct. That's my understanding, that sometime this fall the 522 study will be concluded and that sometime in the near future that data will be made available.

Q. Prior to the 522 orders was the use of polypropylene mesh transvaginally for the treatment of pelvic organ prolapse within the standard of care?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. While it was not outside the standard of care, for many products there was no long-term data. There is no prospective randomized control trials of greater than one year.

When you look at the few studies that have been done past one year, there is a -- the Milani study on the Prolift device that showed a 42 percent erosion rate at five years for the Prolift device. It is very difficult with one-year data on products in nonrandomized control trials to be able to prove the safety and effectiveness of a product.

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BY MS. STEELE:

Q. So prior to 2012 when the 522s were ordered, the use of transvaginal mesh for the treatment of pelvic organ prolapse was within the standard of care, correct?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. It was not outside the standard of care.

BY MS. STEELE:

Q. Have you reviewed the study protocol for the 522 study on the Uphold Lite device?

A. Yes. I reviewed that a while back.

Q. And the Uphold Lite is made of Marlex polypropylene?

A. Correct.

Q. Do you have any criticisms of the study protocol that was approved for the Uphold Lite 522 study?

A. No.

Q. Do you have any criticisms -- first, strike that. Have you reviewed the protocol for the postmarket study being conducted comparing the Solyx single-incision sling to the Obtryx

transobturator sling?

A. Yes, I did review that study protocol.

Q. Do you have any criticisms of that study protocol for the Solyx and Obtryx?

A. No, I have not, and it's my understanding that that 522 study has been completed. However, the data has not been made available yet, at least I haven't seen the data made available yet.

Q. Once the Solyx and Obtryx study data is made available, what rate of cure would you need to see to prove that the devices are effective?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. I don't understand your question.

BY MS. STEELE:

Q. Once the 522 data from the Obtryx and Solyx study is made publicly available, is a cure rate of 80 percent acceptable?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. For demonstrating effectiveness?

BY MS. STEELE:

Q. Effectiveness.

A. After the three years?
Q. Correct.
A. That would be the efficacy rate. That number would be then made available to patients to give them the opportunity to decide is that an efficacy that they would find acceptable.
Q. What complication rate demonstrated through the Obtryx and Solyx 522 study would change your opinion regarding the safety of those products?
MS. HUTSON: Object to the form.
BY THE WITNESS:
A. The literature on polypropylene, the fact that polypropylene degrades, that polypropylene contracts. There was a systematic review by Thomas in 2018 that showed that for polypropylene products, the chronic inflammatory reaction has not been shown to ever go away.
So we know that there is a chronic foreign body reaction that never goes away, a chronic inflammatory reaction that never goes away, that the mesh degrades, the mesh contracts, that the mesh -- there is no time that there will ever be a resolution of the risk

of having complications, complications of pelvic pain, dyspareunia, urinary issues, recurrent incontinence, overactive bladders, obstructed voiding, mesh erosion, mesh exposure into the vagina, erosion into the urinary tract.

There is no time that that would ever be absolved in a patient from that occurring, that removing mesh once it's been put in place is impossible, that patients will have multiple -- will need multiple revision surgeries that might not resolve their problem. So there is no complication rate that is documented in this 522 study that will prove that this device is safe and effective.

BY MS. STEELE:

Q. So no matter what the study protocol is, there is no study that could ever be designed that would prove polypropylene mesh is safe for placement in the female pelvis; correct?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. A three-year study, it's still too short. Remember, this mesh is going to be

placed for the lifetime of a woman, okay? There is data that complications show up ten, 15, 20 years after implantation. So that a short-term data -- three years is an intermediate term -- it just gives you a number of what this study found.

BY MS. STEELE:

Q. How much -- how long of a follow-up is good enough?

A. As I've stated in my report, polypropylene is not an adequate material to be placed in a female pelvis. Polypropylene is attacked by strong acids, peroxides that are readily available in the pelvis. Polypropylene is not pure. It contains a multitude of additives that will leach out over time.

The polypropylene will degrade. It will contract. It will have a chronic foreign body and it will have a chronic inflammatory reaction. So all the opinions that are in my general causation report about the Solyx and the Obtryx device will not change based on the results of the 522 study.

Q. You've criticized Boston Scientific for

not conducting studies on its polypropylene mesh products, correct?

A. Correct.

Q. And you've criticized the reliability of various studies that have been published in the literature regarding Boston Scientific's mesh products, right?

A. They are as stated in my report, as stated in my testimony, correct.

Q. What study could Boston Scientific have done that would have been good enough for it to market its polypropylene mesh products?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Well, again, doing this study is a start, and it gives numbers that can be used to counsel a patient about the risks associated with these devices. Again, there are other risks such as the risk of mesh degradation, the risk of mesh contraction, the risk of the chronic foreign body reaction, the risk of chronic inflammation, the risk that these will never go away, that these can lead to multiple complications that can never be treated, that

even with treatment you will not resolve complications.

That is what I talk about in my section on Directions For Use. So yes, doing a study we'll be able to say, In three years we found that the success rate of the Obtryx was 85 percent and the success of the Solyx was 72.5 percent, that the erosion rate -- which we know from the Ross study from Obtryx, a five-year study -- the erosion rate was nine percent, the rate of pelvic pain was 15 percent, the rate of abdominal -- excuse me -- the rate of groin pain was 15 percent, the rate of abdominal pain was 40 percent.

That is important numbers to be able to give to a patient to counsel the patient. So the 522 study is going to be one point, okay? There are other points. The only long-term randomized control trial on Obtryx, on Advantage is the Ross study. It's the only good study that's in the literature, and that shows that there -- for the Advantage mesh, there is a 12 percent erosion rate. When you add the Obtryx with the Advantage arm, you get a 12 percent

erosion rate. That is a significant number.
BY MS. STEELE:
Q. The Tarcan study has five-year randomized data --
A. Tarcan is not --
THE COURT REPORTER: I'm sorry. Can you wait until she finishes? Ask your question again.
BY MS. STEELE:
Q. The Tarcan study has five-year randomized data?
A. No, it does not. The Tarcan took eight years to do. They only looked at a year and a half's worth of data, and they state that the reason why it took so long is they were spending more of their time removing mesh than putting mesh in. Tarcan is not -- I've had a long discussion with Mr. Adams about the Tarcan study.
Q. I believe you said it was an obscure Turkish study?
A. It was published in an obscure journal, unlike the Ross study that was in peer-reviewed journal.

Q. And the authors in the long-term Ross article do not recommend doctors discontinue using the Advantage or the Obtryx, correct?

A. I do not specifically recall their recommendation. I do recall that their first study stated that the transobturator sling is at a disadvantage to the retropubic sling because of the data on palpable mesh, groin pain. This further showed the erosion rate associated with it.

MS. HUTSON: I'm going to give you a lot of leeway, but these specific studies he has testified about a number of times, and today is supposed to be limited to new opinions. I'm going to give you some leeway, but I just wanted to address that.

BY MS. STEELE:

Q. Would the only study that you would not have criticisms of to prove the safety and effectiveness of Boston Scientific's polypropylene mesh products be a lifetime follow-up study that is prospective and randomized?

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. A long-term prospective randomized control trial gives very good data. However, you have to look at it with all of the other data points that we have there; all the studies that have looked at mesh degradation, the studies that have looked at mesh contraction, the studies that have looked at the chronic foreign body reaction, chronic inflammatory reaction, and the risks that are generated from those or the complications that are generated from those defects of the polypropylene mesh.

BY MS. STEELE:

Q. So really no matter what study Boston Scientific did before marketing its polypropylene mesh products, the polypropylene mesh products still will not be safe in your opinion, right?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. The information that has come out since these products have been on the market shows the defects in the product, the design defects that cause the harm that has been -- that I've

discussed in my report.

BY MS. STEELE:

Q. And I won't go into the details of the studies with Costello and Clave on degradation, but have you reviewed subsequent more recent literature on degradation of polypropylene mesh?

A. The first study was actually the Wang study, and nobody really talks about that. Wang in 2004 looked at recurrent erosions and found that those were associated with fragmented mesh.

In 2004 Wang -- and Wang is by far, next to the Scandinavian group, one of the largest -- was one of the largest users of midurethral slings and found that those were associated with fragmented mesh and stated that mesh degrades and that this should be looked at epidemiologically, so it really wasn't Clave. And if you look back at -- you know, polypropylene suture was first introduced in 1960.

By 1970s there were already reports of problems with polypropylene suture. There was fragmentation, splitting, cracking of the polypropylene suture which led to the Celene

Mary study in 1998 that said that there had been significant reports of problems with polypropylene suture.

She did a study in an animal model comparing polypropylene with PVDF and showed that there was significant degradation of polypropylene and no degradation in PVDF.

Now, there has been a significant amount of literature recently with the Neal study, the hydrology studies, the Zimmern study, and there are other studies that say that this is not fragmentation of mesh. This is just absorbed protein or biofilm. Biofilm is not a good thing, as my report illustrates.

It's a polysaccharide deposited by bacteria. So when you see biofilm, that tells you that you have a subclinical infection. So there are a number of papers that describe the degradation process, that describe the degradation process of women with complications. There are other studies that say that yes, there is surface cracking but we attribute it to something different.

Q. Did you review the article by Dr. Timms

and his colleagues?

A. Yes.

Q. Do you have criticisms of that article?

A. Again, there are -- having explanted 350 polypropylene products, I have found the mesh brittle, hardened and stiff. That's what happens with degradation.

Q. So do you have criticisms of Dr. Timm's article?

MS. HUTSON: Form.

BY THE WITNESS:

A. There are points in the literature. If you want to pull out the study in particular and we can walk through the Material and Methods section, we can walk through their conclusions, then we can do that.

BY MS. STEELE:

Q. So not any specific right now besides his ultimate conclusion that it doesn't degrade?

A. Correct.

Q. How many hours did you spend preparing your updated report?

A. I don't specifically recall.

Q. How many hours did you spend preparing

for your deposition?

A. Ten, 12 hours.

Q. What is your current hourly rate for review?

A. 750. It has not changed since the last time you saw a fee schedule.

Q. And you consult with plaintiffs' counsel to offer opinions regarding various mesh manufacturers; is that right?

A. In this litigation?

Q. Yes. The mesh -- various mesh manufacturers in the pelvic mesh litigation.

A. I also consult with the U.S. Attorney's office and various Attorney Generals in the United States on mesh issues.

Q. What is the total amount of money that you've been paid by plaintiffs against the various manufacturers in the pelvic mesh litigation?

A. Are you talking about the U.S. Attorneys, Attorney Generals? Because I'm not at liberty to discuss any of that information.

Q. Just from plaintiffs.

A. I do not have that number.

Q. I believe in 2015 you testified that you had been paid approximately two and a half million dollars; does that sound right?
A. I don't specifically recall that number. If you have that testimony...
Q. Since -- in 2018 how much have you been paid by plaintiffs' attorneys in the mesh litigation?
A. That I don't know.
Q. No estimate?
A. I don't keep track.
Q. In 2017 how much were you paid by plaintiffs' attorneys in the pelvic mesh litigation?
A. I don't know.
Q. Was it $10,000?
A. No.
Q. Was it $200,000?
A. Probably more than that.
Q. Was it more than $500,000?
A. Possibly.
Q. Was it a million dollars in 2017?
A. That I don't know.
Q. So if it's half a million, a million,

you just don't know?
A. Correct.
Q. In 2017 what percentage of your income was derived from litigation and consulting?
A. Again, I don't think I can answer that question.
Q. Is it fair to say in 2017 you earned somewhere between 500,000 and $1 million from plaintiffs in the pelvic mesh litigation?
A. Possible, yes.
Q. Has that number been consistent over the years since you first started consulting or has it increased?
A. It's been about consistent.
Q. And you mentioned that you've removed 350 mesh products approximately?
A. Correct.
Q. And at times you're able to identify what manufacturer the mesh product was from because you have the records of the patient, right?
A. Correct.
Q. And I believe you've already previously testified about your experience removing Boston

Scientific's three retropubic slings, so I want to just ask you about the other products, okay?

A. Yes.

Q. Approximately how many Boston Scientific Obtryx slings have you removed?

A. I do not specifically recall the number that I gave prior, so it would be more than that.

Q. Do you have a number total or not at all?

A. Whatever I testified to previously, it would be more than that. I don't know, 20 maybe, 15.

Q. How many Boston Scientific Prefyx slings have you removed?

A. I think only one.

Q. Do you recall the circumstances of that case?

A. No.

Q. How many Boston Scientific Solyx slings have you removed?

A. Again, a handful.

Q. How many Boston Scientific Uphold devices have you removed?

A. A couple.

Q. How many Boston Scientific Pinnacle products have you removed?

A. A couple, and, you know, like around a half a dozen. When I'm saying a couple, I'm meaning about a half a dozen.

Q. And I believe your 2014 report, feel free to refer back to it, had -- you had removed around 300 mesh products at that time?

A. Correct.

Q. So over the past about three, three and a half years, you've removed an additional 50 mesh products?

A. Around that ballpark.

Q. So that's approximately once or twice a month you perform a mesh removal?

A. Correct.

Q. And you've never implanted a Boston Scientific Prefyx sling, correct?

A. Correct.

Q. You've never implanted a Boston Scientific Solyx sling, correct?

A. Correct.

Q. You've never implanted a Boston

Scientific Uphold, correct?

A. Correct.

Q. You've never implanted a Boston Scientific Pinnacle, correct?

A. Correct.

Q. Have you ever used the Boston Scientific Capio in any of its forms?

A. Yes.

Q. What Capio devices do you use and for what procedure?

A. I use the Capio device to do sacrospinous ligament fixations. I've used it to do arcus tendineus suspensions. I don't use it for uterosacral ligament suspensions.

Q. And to talk about your general care and treatment of patients with pelvic organ prolapse, what is your primary procedure to treat anterior prolapses?

A. Anterior colporrhaphy.

Q. And what type of suture do you use?

A. Absorbable suture, PDS, Monocryl.

Q. What is your primary surgical procedure to treat apical prolapse?

A. Either uterosacral ligament suspension

or sacrospinous ligament suspension.

Q. And what is your primary procedure to treat posterior?

A. A posterior colporrhaphy.

Q. How often do you perform surgery to treat pelvic organ prolapse?

A. Several times a month.

Q. How often do you perform a repeat procedure on a patient with pelvic organ prolapse?

MS. HUTSON: Object to form.

BY THE WITNESS:

A. Several times a year.

BY MS. STEELE:

Q. Do you tell patients a failure rate for anterior repairs?

A. I tell them that there is a study by Lavelle that came out in 2016. It said the rate of anterior recurrence is 7.3 percent. I also quote the Denman study that came out in 2008 which is a ten-year follow-up of both stress incontinence and prolapse surgery and the recurrence -- the repeat surgery rate was 17 percent after ten years.

Now, I also quote them that the untreated compartment, there is a higher failure rate in the untreated compartment, so that if you do an anterior repair but you don't treat the apical and posterior compartment, that there can be as high as a 25 to 30 percent prolapse in the secondary or untreated compartment.

Q. And for an apical repair what reoperation rate or recurrence rate -- those may be two different -- do you cite or is it the same numbers?

A. I would put it all in a global. I mean, if someone has a site-specific defect, then a site-specific repair would be indicated. I think most of us feel that an apical repair is indicated along with an anterior-posterior defect unless it's a site-specific defect, and, therefore, an apical repair would be done with the anterior-posterior repair whether or not it's done in conjunction with a hysterectomy or if there has been a prior hysterectomy performed.

Q. For all three areas of compartments of repair, do you cite that 7.3 to 17 percent?

A. Well, that was from a specific study.
Q. Specific study?
A. That was for anterior, but the Denman study was for prolapse in general. So if I was going to be talking about prolapse in general, I would say in ten years you have about a 15 to 20 percent chance of needing another surgery.
Q. So for the prolapse repairs that you perform not involving polypropylene mesh, you counsel your patients that there is a 15 to 20 percent chance at ten years that they'll need another surgery?
MS. HUTSON: Object to the form.
BY THE WITNESS:
A. Based on the literature, yes.
BY MS. STEELE:
Q. Do you track your own recurrence rate, failure rate?
A. No.
Q. And I believe your report discusses the study by Abbott?
A. Correct.
Q. And that patients seek care at tertiary centers and don't return to their original

doctors is one of the --

A. Abbott, Blandin both say that there is a significant number of patients with mesh complications, not just recurrence of symptoms, but mesh complications dealing with pain, dyspareunia, erosions, voiding dysfunction, defecation disorders go to a secondary provider.

Q. And you have never published your data regarding your removal of polypropylene mesh, correct?

A. Correct.

Q. And you've never performed any chemical testing of polypropylene mesh, correct?

A. In what respect?

Q. You've observed mesh that you've explanted?

A. Correct.

Q. Have you ever performed chemical testing of the mesh such as scanning, electron -- that's not chemical but --

A. That's right.

Q. -- have you conducted FTIR testing --

A. That's not chemical.

Q. -- or EDS?

A. That's not chemical.
Q. You wouldn't consider those chemical tests --
A. No.
Q. -- to determine the chemical composition of the polypropylene?
A. See, you're not -- when you're saying to determine what has happened to it, has it lost molecular weight, has it, you know, changed its density at all, that's different from adding a chemical to it to see how that reacts.
So when you say a chemical test, that means taking like peroxide and putting it --
Q. And adding --
A. -- on it and seeing what happens.
Q. Again, in vitro tests?
A. Right.
Q. So you've never conducted FTIR on polypropylene mesh, correct?
A. Correct.
Q. And you've never conducted GPC on polypropylene mesh?
A. Correct.
Q. You've never performed SCM on

polypropylene mesh?

A. My SCM machine has been in the shop for awhile.

Q. Maybe they could get it fixed for you.

A. It's tough to find parts for them.

Q. I believe it. Have you ever conducted EDS or XPS testing on explanted polypropylene mesh?

A. No. But if you looked at my CV, you will see that I did SCMs on latex condoms.

Q. Do you agree that reasonable doctors can use polypropylene mesh transvaginally for the treatment of pelvic organ prolapse?

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. In an experimental protocol, yes.

BY MS. STEELE:

Q. We discussed the numbers for recurrence or reoperation you counsel your patients on with prolapse repair.

Do you counsel your patients undergoing prolapse repair on the risk of pain?

MS. HUTSON: Object to form.

///

BY THE WITNESS:

A. Yes, in the postoperative period.

BY MS. STEELE:

Q. Do you counsel them that there is a chance of chronic pain?

A. It is exceedingly rare to have chronic pain after a pelvic organ prolapse procedure, particularly if you -- with a posterior colporrhaphy it was considered more of a standard practice to do a levator plication, and the data on levator plications in pain and dyspareunia show that there was a high rate of pain with levator plication with posterior repair.

So unless there is a specific defect in the levator muscles that's leading to an invagination of the small bowel in between the vagina and the rectum because of a levator defect, then you would be repairing a levator defect specifically, but that would not be a general posterior repair. So if you avoid the levator plication in all patients that have just a posterior defect, you will decrease the rate of pain down to an exceedingly low level.

So the studies found a four percent postoperative dyspareunia rate when a levator plication is not done. And then if you have to do a levator plication and you use a delayed absorbable suture instead of what we thought before as using a permanent suture, that further decreases the rate.

Q. Do you counsel your patients that there is a risk of chronic pain following prolapse repairs?

A. There is an incredibly small risk of chronic pain with prolapse repairs.

Q. And you counsel your patients to that effect?

A. Correct. What I also counsel my patients about is that if they have pain postoperatively and the pain continues, that is the chronic pain. But what they won't have is healing up after their postoperative period and then at a time one to two years later, because of mesh contraction, degradation, chronic foreign body reaction, chronic inflammatory reaction, the new onset of pain that becomes chronic.

That is the difference between native tissue repairs for both prolapse and stress incontinence and polypropylene mesh repairs, that if there is pain in the postoperative period that continues and in the very rare occurrence becomes chronic, it was there since the time of surgery. Mesh is unique that you can have that pain plus you can have pain that starts a year, two years, five years after that is due to the defects of the device that I describe in my report.

Q. Can you on clinical examination detect mesh contracture?

A. Yes.

Q. What would the clinical findings be?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Well, normally the -- or ideally there is supposed to be tissue integration so that you have fat blood vessels that grow through the pores of the mesh, but what happens is because of the chronic foreign body, chronic inflammatory reaction, you get granulomas that form around the individual fibers, and when they

touch, that creates a scar plating. And as the mesh contracts, it becomes tense, firm, and hard.

So yes, that is very demonstrable on pelvic examination. However, we've discussed that in multiple case specific and general causation reports -- depositions.

BY MS. STEELE:

Q. Do you agree that Polyform is a Type I polypropylene mesh?

A. Of the old M classification that even the International Urogynecology Society and -- or the International Urogynecology Association and the International Continence Society has said that was obsolete. The Amid classification which came out in 1998 was looking at pore size as a -- in relationship to infection. As recently as 2013, 2012, IU and ICS came out and said that M classification is obsolete.

Q. Polyform is a Type 1 polypropylene mesh according to the Amid classification, right?

A. So we're talking about the Polyform in Pinnacle and Uphold --

Q. Right.

A. -- which has a pore size of 1.4 and it has a mesh density of 40 or 45 grams per meter squared.

Q. Correct.

A. So my answer to that question is it has a pore size of 1.4 millimeters.

Q. At the time the Pinnacle and Uphold were launched on the market, they were relatively higher weight than the competitor meshes on the market, weren't they?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. The competitor mesh, Gynemesh PS has a density of 45 grams per meter squared. The Apogee, Perigee has a density of approximately 50 grams per meter squared, so it is in the same range of density in grams per meter squared as the other meshes that were on the market.

Now, you know at the same time that the Uphold and Pinnacle were on the market Prolift Plus M was being introduced onto the market and that had a density -- it had an absorbable component which is the Monocryl, so it goes in at 55 grams per meter squared, but within three

months its density goes down to 28 grams per meter squared because the Monocryl is absorbed. The pore size goes to about 2.2 to about 3 to 5 millimeters after the dissolution of the Monocryl component.

BY MS. STEELE:

Q. No matter what the density of a polypropylene mesh for the treatment of pelvic organ prolapse is, you would find it defective, correct?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. No. Based on the work that was done by the Moalli group, that heavier weight smaller-pore mesh is stiffer, and stiffness is one of the characteristics that leads to complications.

So if you look at stiffness and Ultrapro is less stiff than -- based on the Shepherd data -- than all the other lightweight, even Uphold Lite, it is less stiff than any of the other lightweight mesh. It is also less stiff than Gynemesh PS.

Now, what they did is they took

Ultrapro and put it in a baboon model and they found out that because of the stiffness, stiffer mesh causes more harm to the vaginal tissue around it and the smooth muscle tissue around it. So then they went back and said, Well, what is causing this harm? And they found out that stiffer mesh induces bad macrophages, the proactive macrophages that release interleukins and intercrines, and they do one of two things.

They either try to destroy the mesh but indirectly destroy the tissue surrounding it leading to erosion, or they try to encapsulate the mesh by fibrosing the mesh which leads to mesh encapsulation, scar plating and mesh contraction. Both will increase the degree of degradation of the mesh. So stiffer mesh, even if it's the same weight, is bad compared to less stiff mesh.

BY MS. STEELE:

Q. Would you implant Ultrapro for the treatment of stress urinary incontinence?

A. I have said that it is a safer alternative design to a midurethral sling for the treatment of stress urinary incontinence.

Q. Would you implant Ultrapro for the treatment of stress urinary incontinence?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. It's the same question you just asked that I just answered.

BY MS. STEELE:

Q. You believe it's safer but would you implant it into your patients?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. My procedure of choice is the Burch procedure. It has long-term safety and efficacy data.

BY MS. STEELE:

Q. So the answer is no, you would not implant it in your patient?

MS. HUTSON: Objection; form, asked and answered. Go ahead.

BY THE WITNESS:

A. As a midurethral sling?

BY MS. STEELE:

Q. Correct.

A. I would consider it as a pubovaginal

sling, but I have not performed that.

Q. And pubovaginal meaning you'd place it at the bladder neck?

A. Correct.

Q. But you have not performed it?

A. I have not used Ultrapro to perform a pubovaginal sling.

Q. Why wouldn't you use Ultrapro as a midurethral sling?

A. Because it's not available as a midurethral sling.

Q. Have you ever ordered Ultrapro to have on hand at your hospital?

A. I think we have Ultrapro available at our hospital, yes.

Q. Would you implant Ultrapro transvaginally for the treatment of pelvic organ prolapse?

A. As an inlay?

Q. Yes.

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. I have not used that in a pelvic organ prolapse procedure. The ones that I feel need

extra enhancement I've used biological material such as SIS.

BY MS. STEELE:

Q. Your report does not offer any opinions regarding Boston Scientific's biological grafts Xenform and Repliform, correct?

A. Correct.

Q. Will Ultrapro mesh undergo degradation in the female pelvis?

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. More likely than not, yes.

BY MS. STEELE:

Q. Will Ultrapro mesh undergo contracture in the female pelvis?

A. More likely than not, yes.

Q. Can Ultrapro cause chronic pelvic pain if used in the female pelvis?

A. More likely than not, yes.

Q. Can Ultrapro cause dyspareunia if used in the female pelvis?

A. More likely than not, yes.

Q. Can Ultrapro erode through the vaginal tissue or into organs?

A. Yes.
Q. Are there any long-term randomized prospective clinical trials on the use of Ultrapro for the treatment of stress urinary incontinence?
A. Yes.
Q. Long-term prospective randomized?
A. Three years, yes.
Q. Three years is long-term data?
A. Mid-term.
Q. That's one study out of Scandinavia; is that right?
A. I don't think it was Scandinavia. I can't remember where it was from, but it was not from the United States.
Q. Have there been any long-term randomized prospective clinical trials on the use of Ultrapro for the treatment of pelvic organ prolapse?
A. Well, whether it was used as Prolift Plus M but their -- not that I recall on their long-term studies on Prolift Plus M.
Q. Is the Prolift Plus M product defective?

MS. HUTSON: Object to the form.
BY THE WITNESS:
A. Yes.
MS. STEELE: I want to take a quick break.
MS. HUTSON: Of course.
THE VIDEOGRAPHER: We are off the record at 10:24 a.m.
(Recess had.)
(Mr. Ken Moll left the deposition proceedings.)
THE VIDEOGRAPHER: We are back on the record at 10:33 a.m.
BY MS. STEELE:
Q. I want to turn our attention to the Prefyx device specifically.
A. Yes.
Q. And I believe your opinions regarding Prefyx start on page 12 to 13 generally, and then there is some discussion of it throughout the rest of your report as well in connection with your general discussions regarding polypropylene mesh.
Do you have any specific criticisms of

the Prefyx beyond the defects that you've identified in your report regarding polypropylene degradation, contracture, shrinkage, infection and the long-term and severe complications?

A. That are not outlined in my report, no.

Q. Your criticisms of the Prefyx are based on the same opinions that you criticize Boston Scientific's other polypropylene midurethral slings; is that correct?

A. And that there is a higher failure rate associated with putting it in the prepubic space as outlined in my report.

Q. Do you have any other criticisms of the prepubic placement of the Prefyx besides the higher failure rate?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Not specifically that's not outlined in my report.

BY MS. STEELE:

Q. And based on your review of the literature and documents, what were the goals or objectives that led to the development of the

Prefyx?

A. To avoid the retropubic space.

Q. And by avoiding the retropubic space, you decrease the risk of bladder and bowel injury; is that right?

A. Correct.

Q. Do you agree that the use of the Capio device to place the Pinnacle and Uphold made polypropylene kit mesh procedures less invasive?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. It gave an option to make it an exit, an armless procedure without -- excuse me -- longer arms that avoided exit points.

BY MS. STEELE:

Q. Is the use of the Capio to place a polypropylene mesh with arms less invasive than the use of trocars to place polypropylene mesh arms?

MS. HUTSON: Object to form.

BY THE WITNESS:

A. It is -- there is mesh -- with the use of the Capio, attaching the mesh to the sacrospinous ligament means that there is not

mesh in the obturator space or in the ischiorectal fossas.

BY MS. STEELE:

Q. Are the Pinnacle and Uphold procedures less invasive than the predecessor procedures?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. It's a different procedure and there is mesh in different locations or it obviates mesh in certain locations.

BY MS. STEELE:

Q. Is it a benefit to obviate mesh in the -- from the obturator space?

A. If there is no mesh in the obturator space or in the ischiorectal fossa, you have mesh not traversing the obturator muscles or adductor muscles, you are avoiding mesh in those locations.

Q. Do you believe that's a benefit of the Uphold and Pinnacle devices?

MS. HUTSON: Object to form.

BY THE WITNESS:

A. Do I believe that it's a benefit? It's been touted as a benefit. Do I believe that

that's a benefit? Having mesh that is not in an area means that you don't develop -- you will not develop complications in that area.

BY MS. STEELE:

Q. So if you don't have mesh in an area, you won't develop complications in that area, correct?

A. Correct.

MS. HUTSON: Object to the form.

BY MS. STEELE:

Q. The use of the Capio allows the Pinnacle and Uphold procedures to be performed through a single vaginal incision, correct?

A. Correct.

Q. The predecessor kits, you also had external exit points for the trocars, correct?

A. Correct, until the Elevate came along.

Q. Are you critical of doctors for using the Pinnacle and Uphold to treat pelvic organ prolapse today?

MS. HUTSON: Object to the form.

BY MS. STEELE:

Q. Not today but -- strike that.

A. Okay.

Q. Are you critical of doctors for using Boston Scientific Pinnacle or Uphold to treat pelvic organ prolapse prior to 2013?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. I am not critical of physicians because it would be difficult to impossible for all of the information and risks associated with the device to be understood and obtained by a given physician because that information was not in the Directions For Use.

The information about these devices, the risks, the defects of the devices, the risks of lifelong pain, dyspareunia, erosion, mesh contraction, the difficulty or impossibility of mesh removal, the frequency, severity, treatability and permanency was not described in the Instructions For Use. It was not studied prior to being placed on the market. All the things that I describe in my report.

So I can't be critical of doctors because it would be virtually impossible for them to have read the literature at that time or even the literature today to be able to know

what all the risks associated with these devices were. So no, I am not critical of an individual doctor for implanting mesh before 2013.

BY MS. STEELE:

Q. Do the Pinnacle Directions For Use warn of the risk of mesh contracture?

A. If you would like to pull out the Directions For Use, we can go through each of the items in the Directions For Use. What's in the Directions For Use is in the Directions For Use.

If I recall, that the word "contraction" is in the Instructions For Use. That is not an adequate description to say that the risk of mesh contraction is lifelong, that when mesh contracts it draws nerves closer to the mesh.

There are nerves that grow through the mesh that are then injured by the mesh contraction. That mesh contraction will harden the mesh. That mesh contraction will degrade the mesh, that it will put tension on the vagina, it can change the vaginal topography to make intercourse impossible. So just saying

"contraction" -- all of these words that are in the Instructions For Use are words that are in the Instructions For Use.

It doesn't give you indications of the frequency, severity, treatability and permanency of those events, so just saying "contraction" is not adequate to describe what the risks are of these devices, as I've stated in my report and as I've testified to in prior depositions and trials.

Q. Have you ever attempted to construct a DFU for the Boston Scientific polypropylene mesh products that would be adequate in your opinion?

MS. HUTSON: Object to form.

BY THE WITNESS:

A. I can't remember if I was asked that specific question, but yes, if we would want to take out a piece of paper and a pencil, we can take what is there. We can add to that the lifelong risk of dyspareunia, the lifelong risk of mesh erosion, the lifelong risk of mesh contraction, that if this occurs, that the treatment -- even now after polypropylene mesh products have been used for 20 years, there is

no standard reproducible agreed upon method of removal.

It is not for a doctor to use trial and error to learn how to remove mesh. It is not up to a doctor to say, Oh, my gosh, look at this complication that I have, which is why many patients get sent to other doctors that have gone through that trial and error process.

I mean, there are textbooks that say if you have a bladder injury, a complication, this is how you fix it. If you have this injury, this is how you fix it. There is nothing like that for treating mesh complications. There is nothing like that for removing mesh. That is incredibly important for doctors to know.

That is incredibly important to be in the Directions For Use. There needs to be a range of the risk of mesh exposure. Patients don't want to know that, Well, it might be as low as three percent or six percent or eight percent, because this one study that was a cohort study that only followed patients for a year that might have only had a follow-up of 50 percent found that number.

Patients want to know what is the worst-case scenario. What is the worst that could happen? That is why it is imperative to put a range of frequencies in the Instructions For Use.

The severity, how bad can this be? Just saying dyspareunia doesn't tell you that you might never be able to have vaginal intercourse again. That has to be in the Instructions For Use. Because yes, there are for SUI 2,000 plus papers, for POP close to 1,000 papers. Doctors don't have the opportunity to read that.

The manufacturer has that responsibility to know that. And particularly for these devices, the vast majority of these publications are abstracts presented at meetings. If you didn't go to the meeting, if you didn't go, happen to see the journal that it might have been published in, you wouldn't know that abstract. I have been criticized for not knowing about an abstract that I couldn't find, and I've been working on this for eight years, okay?

How is a doctor that is just seeing patients every day supposed to find an Agrawal 2006 abstract or the Litwiller abstract or the Rosenblatt Pinnacle abstract that has the long-term follow-up of 27 months? Which isn't long term but that's what the title says.

How are you supposed to find those abstracts? It's very difficult to find them to see what the, quote-unquote, literature says unless it is a -- the full-length paper is described. So yes, that would be the way to put together a Directions For Use with warnings, adverse reactions, things like what are relative contraindications?

We know smoking increases the risk of erosion. We know that vaginal atrophy, which every women that hits a certain age is going to develop menopause and the genitourinary symptoms of menopause.

What about pretreatment with estrogen? What about women that happen to be a little bit bigger that have a greater risk of erosion? So why aren't all of those in the Instructions For Use? That I would put in the Instructions For

Use these relative contraindications. The Withagen paper talked about women that have pain syndromes, particularly pelvic pain syndromes.

Chip Butrick writes papers all the time about women that have levator tension myalgia. Those are women that are at increased risk from slings and mesh to have postoperative pain syndromes. That should be in the Directions For Use. So yes, we could spend several days putting together an adequate Directions For Use that would have all of that information that's in there.

I think I might have answered 12 questions in that one question.

BY MS. STEELE:

Q. Thank you.

A. I did, and I thought this might be a good time to kind of get all those out.

Q. Let it out, yeah. Quick therapy session.

A. It is kind of like that. That's what these depositions are.

Q. You agree that pelvic organ prolapse is a serious condition that does not improve on its

own?

A. It's a compound question, okay? Mostly it's a quality of life issue, okay?

I published a paper years ago that showed that even with worsening pelvic organ prolapse, you don't characteristically have obstructive voiding. That is the exception. Most women have the symptom of increasing pressure in the vagina as the day goes on, so while yes, it can be a -- it can lead to bowel dysfunction, it can lead to urinary dysfunction, it can lead to discomfort with intercourse because there is this other thing there in the vagina besides what is supposed to go in the vagina during intercourse. For most women it's just a quality of life issue, I mean, the vast majority.

Q. So pelvic organ prolapse can affect a women's quality of life, right?

A. Correct. Now, there -- yes, it can get better on its own because what happens is that as a woman ages, there can be more, you know, atrophy and contraction of the vagina, and I have seen women that as they get older, their

prolapse does get better. So yes, it can get better. That's why I wanted to divide up the compound question.

Q. How likely is it that a prolapse will get better on its own as a woman ages?

A. It is less likely than it staying the same.

Q. Can a prolapse get progressively worse without treatment?

A. Yes, but remember, you know, Dr. Culligan wrote a really nice paper in 2005 about nonsurgical treatment of pelvic organ prolapse and it -- we don't use our brethren in orthopedic surgery in urogynecology. You go to an orthopedic surgeon, and what they're going to tell is, If you keep doing what you did, you know, to tear out your shoulder like my wife did, strain your back like happened to me and needing back surgery and things are kind of getting worse again or blow out your knee, you're going to continue to have problems.

We don't do a good enough job to get the corollaries of prolapse like defecation disorders. We do a poor job of treating

defecation disorders. The more you strain, the more likely you are to worsen your prolapse. The more you lift heavy things, the more you do not treat pulmonary dysfunction, the more likely prolapse is to get worse. And so physical therapy is great to avoid worsening orthopedic disorders.

Same thing with pelvic organ prolapse because what you're doing is you're doing your -- using your ancillary muscles instead of using your pelvic floor muscles so that you're not straining your pelvic floor muscles. But if you continue to do the things that, besides aging and childbirth which develop the prolapse, if you continue to do things that worsen the prolapse, yes, it's going to get worse.

But if you modify behavior, yes, you can keep prolapse at bay, and at the point where prolapse becomes symptomatic when it hits the hymen by -- you know, most -- Barbara's study, Barbara Brubaker's study from 2008, you know, prolapse hitting the hymen is where it starts to become symptomatic. So if you can keep it there and keep it asymptomatic, you are effectively

treating the prolapse.

Q. So without behavioral modification, a woman's prolapse can get progressively worse, right?

A. Yes.

Q. Do you agree that pelvic organ prolapse can have an impact on a woman's life?

A. Quality of life, yes.

Q. Do you agree that there are patients that come into your office with pelvic organ prolapse where no treatment is no longer an option?

A. Oh, there is always a treatment. Pessary -- you know, 75 percent of women can be fit with a pessary. Dr. Culligan again wrote in 2004 that the vast majority of women can be treated with a pessary.

Q. Yeah. I think we spoke past each other. When not treating the prolapse is no longer -- strike that.

Do you agree that there is patients who come in to you with pelvic organ prolapse where no longer -- or not treating the prolapse is no longer an option, just observing is no longer an

option?

A. Oh, so observation being the treatment, that you move from that treatment to another treatment, a more active treatment?

Q. More active treatment.

A. Yes.

Q. Do you agree that there are patients with pelvic organ prolapse where surgery is necessary?

A. Where surgery is an option, yes. But again, you know, quoting Dr. Culligan's study, there was just a study this year that talked about the metrics of prolapse surgery and documenting that, you know, the patient had treatment with physical therapy, and a pessary prior to going to surgery is one of the quality metrics that are being measured, and that that means that those are things that should be offered prior to surgery and encouraged because again the vast majority of women can be fitted with a pessary, and a pessary really is not an inconvenient treatment for pelvic organ prolapse.

It's like wearing a brace. You take it

off, you clean it off at the end of the day, and when you're doing your activities that lead to your symptoms, you put it back on again.

Q. Do you agree that for some women wearing a pessary is inconvenient?

A. If they're not counseled appropriately, if they're not fit appropriately, there are woman that choose not to use it.

Q. Pelvic organ prolapse can become so severe that a women can have a bulge coming out of her vagina outside her body, correct?

A. Correct.

Q. You agree that pelvic organ prolapse can cause vaginal pressure?

A. Correct.

Q. Do you agree that pelvic organ prolapse can cause pain for some women?

A. Correct.

Q. Do you agree that pelvic organ prolapse can prevent a woman from engaging in sexual intercourse?

A. It can make sexual intercourse uncomfortable.

Q. Is there a stage of prolapse where a

pessary is no longer an option?

A. No.

Q. Do you agree that pelvic organ prolapse is something that doctors have struggled to surgically fix for hundreds of years?

A. I'm struggling with "struggle." I mean, every surgery is unique and every surgery has difficulties. Some -- even the most benign and simple procedure can turn untoward and even the most complex surgery you go in thinking, It's going to be the worst day of my life in the operating room, and you walk out going, Well, that was pretty easy. So surgery is unique.

Q. Do you agree that the perfect surgery to fix prolapse hasn't been found yet?

A. I would definitely agree with that.

Q. Do you agree that with every prolapse surgery a women has to undergo, her risk of recurrence increases?

A. If she does not do the things that made the prolapse worsen. So if you continue to put a stress on a fascial structure, that fascial structure is going to give way. So unfortunately most people don't want to modify

their behavior, and so they are going to continue to expose themselves to that risk, but they are -- with any treatment you're going to have the risk that -- of recurrence.

Q. So, for example, with the studies that you discuss with your patients regarding reoperation --

A. Yes.

Q. -- being somewhere in the range of 15 to 20 percent at ten years?

A. Correct.

Q. So if a women has a prolapse repair at age 40, by age 50 she has a 15 to 20 percent risk that her prolapse will have recurred; is that right?

A. Correct.

Q. If she undergoes another surgery at age 50 to correct her prolapse, does her recurrence rate then increase over the next ten-year period?

MS. HUTSON: Object to form.

BY THE WITNESS:

A. The Denman study did not stratify out primary versus recurrent procedures, but I think

one would state or one would intuitively agree that a repeat operation is going to be fraught with a greater chance of recurrence.

BY MS. STEELE:

Q. In what patients do you utilize a biologic graft to reinforce the repair?

MS. HUTSON: Object to form.

BY THE WITNESS:

A. That would be on a case-specific basis it would be done. I would have to see the patient in front of me.

BY MS. STEELE:

Q. Is it based on -- for what other case-specific factors? Is it severity, is it prolapse?

A. It's the uniqueness of the prolapse. One case that comes to mind of a woman that had a bulge in her perineal body and it was a separation of the rectal vaginal septum and a dissection of the levator muscles, and the small bowel was just bulging between the vagina and the rectum and there was just -- it increased the perineal body and there was a bulge of tissue that came down and that was a unique case

that the only way to support the structures was by using an interposition of a biologic.

Q. In how many surgeries per year do you incorporate the use of a biologic graft?

A. I haven't done one this year. You know, maybe one or two.

Q. And we've discussed that levator plication traditionally if used with a nonabsorbable suturing material has an increased risk of pain with intercourse compared to other prolapse repairs, correct?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Compared to not using a levator plication for a posterior repair, and that is from the time of surgery going forward.

BY MS. STEELE:

Q. How often do you use the Capio device?

A. A couple times a year to do a sacrospinous ligament fixation. It was like two months ago -- we've been having a hard time getting sutures for the Capio, and I was going to do a sacrospinous fixation and we didn't have suture.

Q. What sutures do you use with a Capio?
A. Delayed absorbable, currently at the hospital available or in what's been going on for the last I think four months is non-available.
Q. And do you agree that options for treatment are necessary because patients are very different from one another?
A. Options for treatments vary because patients are different from one another?
Q. Do you agree that options for treatment are necessary because patients are different from one another?
A. Well, in a very broad sense, yes. In a very specific sense, no. Horrible question so I'm giving you a horrible answer.
Q. Well, what -- so in some patients you use a biologic graft, right?
A. In a -- for a very specific defect, not the typical defect.
Q. For some patients you use only an anterior colporrhaphy, right?
A. As a site-specific repair for someone that just has a site-specific defect, correct.

Q. And for some patients you incorporate using a vault suspension?

A. Correct, because most patients would need a vault suspension at the same time of their repair.

Q. For some patients you do a levator plication with absorbable sutures?

A. I don't use a levator plication, no.

Q. At all?

A. No, unless there is a specific levator defect. So that's not doing a posterior repair. That's doing a levator defect repair.

Q. How about for the treatment of stress urinary incontinence? There are different options available because patients are different and need different treatment?

A. Correct, for a primary operation. Burch for women that have recurrent severe stress urinary incontinence, either an injectable or a pubovaginal sling. For overactive bladders, medication. I think for stress urinary incontinence, pelvic floor physical therapy, devices. You know, everything that is in my report are the litany of

nonsurgical treatment.

Q. And it's reasonable for doctors to use biologic slings to treat stress urinary incontinence?

A. As a pubovaginal sling, yes.

Q. And you've testified that it's reasonable for a doctor to use a polypropylene midurethral sling to treat stress urinary incontinence?

A. It is not outside the standard of care.

THE COURT REPORTER: Was that an objection?

MS. HUTSON: Yes, to form.

THE COURT REPORTER: Can you speak up louder?

MS. HUTSON: I'm letting the flow go.

THE COURT REPORTER: But I have to hear it.

MS. HUTSON: I know.

BY MS. STEELE:

Q. And so having all those different treatment options for doctors and their patients to choose from is a good thing, right?

A. It's not a bad thing, correct.

Q. Did you review the Boston Scientific documents that detail the development of the Boston Scientific Pinnacle?

A. Yes.

Q. Did you review the Boston Scientific documents that detail the development of the Boston Scientific Uphold?

A. Yes.

Q. And for both of those devices, the initial idea was brought to Boston Scientific by surgeons, correct?

A. Yes. Dennis Miller --

MS. HUTSON: Objection.

BY THE WITNESS:

A. -- came up with the idea of Pinnacle and Roger Goldberg Uphold.

BY MS. STEELE:

Q. So Boston Scientific didn't come up with the specific ideas for Pinnacle and Uphold; they were brought to them by surgeons, right?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Correct.

///

BY MS. STEELE:

Q. And Boston Scientific did not first come up with the idea of using polypropylene mesh to treat pelvic organ prolapse, right?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Correct.

BY MS. STEELE:

Q. Surgeons had been using polypropylene mesh to treat pelvic organ prolapse since the 1960s?

A. In various embodiments, correct.

Q. Ultimately doctors are trying to find better solutions to treat their patients; do you agree?

A. They were looking for solutions.

Q. Some doctors felt that native tissue repairs had an unacceptably high failure rate that's been reported in the literature, right?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. There -- if you look at the studies that people have used to quote a recurrence rate of 40 to 60 percent, there are some caveats

about that that might not make it generalizable.
BY MS. STEELE:
Q. So Boston Scientific first marketed the Pinnacle device in 2008; is that your memory?
A. That sounds about right, yes.
Q. And the Uphold device was first marketed in 2009?
A. About that, correct. I don't want to spend time going to the exact notation in the report.
Q. And so for approximately 40 years before Boston Scientific marketed a pelvic floor repair kit using polypropylene mesh, surgeons were implanting polypropylene mesh for the treatment of pelvic organ prolapse, right?
MS. HUTSON: Object to the form.
BY THE WITNESS:
A. The first vaginal inlay was credited to Julian in the late '90s. Abdominal colposacropexies had been performed for a longer time than vaginal mesh, and then the TVM group started first with an inlay, then attaching it to the arcus tendineus linea pelvis and then started it with armed mesh products in the late

'90s.

So no. Your statement, while there are reports of mesh being used for abdominal colposacropexies for a long time, vaginal mesh is relatively recent.

BY MS. STEELE:

Q. Ultimately the mesh, even implanted abdominally, with the exception of site passage infection, I think you've testified before that passing the mesh through the vagina exposes it to bacteria?

A. Bacteria, peroxides. There is -- okay. There's a fundamental difference between abdominal colposacropexies and vaginal placement of mesh, all right?

So one is the root, two is the amount of mesh that's actually passed through the vagina, and three is the vector where the mesh is attached, and that -- it makes it very different.

Q. So abdominal sacrocolpopexy mesh will still degrade and it will still contract, right?

A. Correct. And if you look at Nygaard's paper that looks at long-term follow-up, you

have to continue to look at, you know, abdominal colposacropexies because there is no time, even with abdominal colposacropexies, where the patient is free from complications. But remember, the mesh is in a space that the contact with the vagina is much different than transvaginal mesh where it is covering the entire vagina.

So with abdominal colposacropexy mesh you can either attach to the back wall of the vagina, the front wall of the vagina or in a Y shape, okay? So you're only contacting the apical part of the vagina, where transvaginal mesh is contacting the whole anterior wall or the whole posterior wall or the whole anterior apical and posterior wall of the vagina.

Q. And is the Uphold contacting the entire interior wall?

A. It is a smaller mesh, so it's contacting the anterior -- the anterior apical portion of the vagina.

Q. So how much, what grade or percentage of the Uphold is in contact with the vaginal walls than you would see with an abdominal

sacrocolpopexy?

A. Not just the contact. It's the vectors that are also holding onto the mesh, okay? So with mesh that is being attached to two different points in the lateral side of the vagina, roping, deformation, contraction is going to have a greater impact than when you do it with an abdominal colposacropexy where contraction is just going to pull the mesh up.

Q. Even given those differences, you still would not perform an abdominal sacrocolpopexy with mesh, right?

A. I currently do not.

Q. Even if we just consider when companies started marketing polypropylene mesh for the treatment of pelvic organ prolapse implanted transvaginally, there was several years of clinical experience prior to Boston Scientific marketing its pelvic floor repair kits, right?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Correct.

BY MS. STEELE:

Q. Do you have any criticisms of the use

of the Capio?

A. In what respect?

Q. Do you have any criticisms of the Capio device itself?

A. No. I've used the Capio and continue to use the Capio.

Q. And specifically as it's used with the Boston Scientific Pinnacle and Uphold to attach the fixation points for each of those devices, do you have a criticism of the way that the Capio is incorporated into the kit?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Well, the Capio doesn't come with a kit. The Capio is a standalone device.

BY MS. STEELE:

Q. Incorporated into the procedure.

A. The Capio itself?

Q. Yes, or the use of the Capio --

A. I mean, all the Capio is is a suture-passing device to pass it through a fascial structure, so again, I have no problems with the Capio.

Q. Did you review the literature regarding

the procedure that ultimately became the Uphold that were published prior to the Uphold coming on the market?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. The concept of the hysteropexy?

BY MS. STEELE:

Q. The specific procedure --

A. Or the anterior sacrospi --

THE COURT REPORTER: Or the?

BY MS. STEELE:

Q. The procedure that ultimately was marketed as the Uphold procedure.

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. So the anterior sacrospinous ligament fixation and the hysteropexy --

BY MS. STEELE:

Q. Using Polyform mesh.

A. -- that Dr. Goldberg discussed?

Q. Yes. Did you review that literature?

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. Yes.

BY MS. STEELE:

Q. Do you agree that prior to the Uphold being put on the market, there was literature in the form of abstracts regarding Dr. Goldberg's procedure using Polyform mesh in the Capio?

A. Yes.

Q. Do you have any criticism of using the sacrospinous ligament as a fixation point?

A. There are risks associated with the sacrospinous fixation. There are a number of nerves, the pudendal nerve, the levator ani nerve, the sciatic nerve that are all in that area. There are actually several others that are in different locations.

However, I still use the sacrospinous ligament fixation which makes use of the sacrospinous ligament.

Q. Beyond the mesh that's used to pass the legs around the sacrospinous ligament, do you have any criticism of the Boston Scientific Pinnacle or Uphold using the sacrospinous ligament as a fixation point?

MS. HUTSON: Object to form.

///

BY THE WITNESS:

A. It's a suture that is being passed through and underneath the sacrospinous ligament that is then attached to the legs. So it's not the legs that are -- the Capio doesn't attach the legs directly. It's a suture-passing device so -- but beside that caveat, can you repeat your question?

BY MS. STEELE:

Q. Do you have any criticism of the Boston Scientific Uphold or Pinnacle using the sacrospinous ligament as a fixation point?

A. Again, there are risks associated with the use of the sacrospinous ligament. I still use the sacrospinous ligament as an attachment device for sacrospinous ligament fixations.

Q. So no criticisms of the Uphold or Pinnacle for using the sacrospinous ligament as a fixation point, right?

A. As an anatomic structure, no.

Q. Do you have any criticisms of the Boston Scientific Pinnacle for using the arcus tendineus as a fixation point?

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. No.

BY MS. STEELE:

Q. Do you agree that there are patients who have benefitted from the use of polypropylene mesh to treat pelvic organ prolapse?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. I haven't seen that in my practice.

BY MS. STEELE:

Q. Have you seen that reported in the clinical literature?

A. I have seen the clinical literature.

Q. Have you seen anywhere in the clinical literature reported where there are any patients who have benefitted from the use of polypropylene mesh used transvaginally to treat pelvic organ prolapse?

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. I have reviewed the efficacy rates for pelvic organ prolapse treatment using transvaginal polypropylene mesh.

BY MS. STEELE:

Q. And what is your opinion regarding the efficacy rates of transvaginal polypropylene mesh used for the treatment of pelvic organ prolapse?

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. It's not as good as everybody wishes it had been.

BY MS. STEELE:

Q. Do you think that the Boston Scientific Pinnacle was effective in treating pelvic organ prolapse?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. It has an efficacy rate, yes.

BY MS. STEELE:

Q. What efficacy rate do you attribute to the Boston Scientific Pinnacle?

A. In the short term without long-term data?

Q. What efficacy rate?

A. 80 to 90 percent in the short term. There are some that are higher.

Q. What efficacy rate do you attribute to the Boston Scientific Uphold in the treatment of pelvic organ prolapse?

A. The same.

Q. 80, 90 percent?

A. Hm-hmm.

Q. What is the erosion rate of the Pinnacle?

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. It all depends on who you look at. If you look at Shapiro's 2009 or '10 abstract, 27 percent. You can look at some of the other studies that say it's around six percent. So I think the Jeffery study quoted about a 13 percent erosion rate.

BY MS. STEELE:

Q. So the erosion rate with the Pinnacle varies from study to study, right?

A. Correct.

Q. Similarly, the reoperation rate with native tissue or traditional prolapse repair varies from study to study, right?

A. In the randomized control trials

against mesh?

Q. In the literature generally.

A. Correct.

Q. The -- strike that. The risk of using polypropylene mesh to treat pelvic organ prolapse outweigh the benefits in all instances?

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. Well, if you look at the most recent Cochrane analysis by Mayer that the -- there is an increased risk over native tissue repair of reoperation or complications, stress incontinence and recurrence. So in general, yes, the risks outweigh the benefits.

BY MS. STEELE:

Q. Have you done any analysis of the number of women who have benefitted from the use of polypropylene mesh to treat pelvic organ prolapse?

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. I've quoted the most recent Cochrane analysis. If you look at the Stanford study, it shows that there is no difference in efficacy

between native tissue repair and mesh. If you look at the Goldman study, that says that the gold standard for posterior colporrhaphy is native tissue repair. So besides reviewing the literature and being in a clinical practice, that is my review.

BY MS. STEELE:

Q. Boston Scientific still markets Polyform sheet mesh for the treatment of pelvic organ prolapse, correct?

A. As abdominal colposacropexy, yes, to the best of my recollection.

Q. If you turn to page 18 in your report, I want to talk specifically about the sentence that reads, "Polypropylene contains compounds toxic to human tissue that leach out when degradation occurs in the human pelvis, enhancing the intensity of fibrosis and the body's inflammatory reaction."

A. I have that same thing highlighted. I must have read your mind.

Q. It appears we have several of the same things.

A. Okay.

Q. So is your only basis for that statement the Sternschuss article?

A. No. There is the Lithner article. There is several other references that I think are in my other general causation report that describe the leachates that come out of polypropylene.

Again, the polypropylene gets extruded, and prior to the extrusion process to make it into the single sheets it gets mixed up with a variety of compounds that are proprietary to Marlex or proprietary to prolene mesh from other companies, and you guys don't tell us what that is so --

Q. Do you know?

A. -- we don't know what antioxidants you put in. We don't know what colorizers and plasticizers and stabilizers that are in there.

That's one of the problems, is that there are all these other things that -- you know, first of all, it was the late '80s or early '90s when antioxidants were first added to polypropylene because polypropylene was breaking down and so you needed to add antioxidants in

order to slow down the degradation process.

Now, when you're using it to like close the abdomen and things scar and the suture starts to break down, that's okay because the abdomen is scarred, but when you're using it as a support for stress urinary incontinence or for pelvic organ prolapse and the degradation process happens, it not only weakens the support but also increases the surface area, increases the fibrosis, increases the chronic foreign body and chronic inflammatory reaction which then leads to all the complications I talk about in my general report.

Q. Do you know the additives that are incorporated into Marlex polypropylene?

A. No, I do not.

Q. Can you cite a study that discusses the leaching of additives from Boston Scientific's polypropylene mesh?

A. Specifically from the Marlex?

Q. Correct.

A. There is a study by Winstanley found fragmented polypropylene in lymph nodes. Again, the Lithner paper talks about plastics and

additives in general and leaching out. Specifically Marlex, no. There is a paper on -- by Parente from prolene mesh but...

Q. Have you reviewed the study with lead author Talley with Drs. Guelcher, Dunn and Nicola as coauthors?

A. Yes, I have seen that study.

Q. And you understand that's a study that uses an in vitro test?

A. In order to be able to completely and accurately answer your question, I would need to have the study in front of me.

Q. Have you ever seen a study on sterilized ready-to-implant Boston Scientific polypropylene mesh made from Marlex resin where there was a leaching of additives?

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. I have not seen a study that looks specifically at that.

BY MS. STEELE:

Q. Can you tell me what toxic additive is in a Marlex polypropylene used in Boston Scientific's polypropylene mesh?

A. Again --

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. -- antioxidants, stabilizers, plasticizers are the general additives that are placed in polypropylene. Without having the exact formula, which I think is proprietary and you guys keep that under -- or Boston Scientific keeps that under rack and key or lock and key, I can't tell you what's in there. But I can tell you in general from looking at other studies that I've quoted previously, that there are -- we know that antioxidants are in there.

I mean, that's all -- that's been agreed to. So that's one of the additives. Antioxidants are not nontoxic.

BY MS. STEELE:

Q. Are antioxidants toxic in any amount when added to a polypropylene that's extruded into a mesh?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. It has not been looked at long term in humans in the pelvic floor, but I can tell you

that when polypropylene was added, put subcutaneously in a rat model, it led to sarcomas from the International Agency for Research on Cancer so -- and that there is a growing number of cases of polypropylene-associated cancer, so that's one of the toxicities.

Now, I know that there have been -- you know, there was a study from Mayo that looked at epidemiologic data, didn't see an increase in pelvic cancers associated with mesh, but they only followed them out five years, and that's too soon for there to be an increase in the risk of cancers but there is a growing number of cases of cancers being reported.

I had a case of a women that had precancerous changes of her vagina associated with an erosion that happened within three months.

BY MS. STEELE:

Q. Marlex polypropylene has been implanted into the human body since the 19 -- late 1950s, 1960s; is that right?

A. I wouldn't disagree with that.

Q. Has there been any report of widespread cancer relating to the use of Marlex polypropylene in the human body?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Widespread, no. There is growing evidence of cases of polypropylene associated with cancers with midurethral slings and POP mesh. Now, remember, early on mesh was used for hernias in very sick patients, patients that had suffered a significant trauma like war injuries. That was the main group.

So their life expectancy and their medical condition is not the same as putting it in a 40-year-old healthy woman that is going to live for another 45 years. I think the average female life expectancy right now is 85 years.

BY MS. STEELE:

Q. Now, hernia mesh is used more widespread, right, over the last 40, 50 years?

A. More widespread since like the '90s. So we're at the 20-year mark. But you know when other synthetic products were used such as Dacron grafts, there are studies -- I'm blocking

on the name, but I think it's in my report or in one of my earlier reports, of leiomyosarcomas being associated with these Dacron grafts, so synthetic material.

Now, Dacron might be more reactive than polypropylene so it sets up a higher chronic foreign body reaction, but it's the chronic foreign body reaction that leads to in certain situations tumor angiogenesis factor or tumor genesis factors to be switched on. Okay? And there is not a lot of research into why that occurs in certain patients, but it will continue to occur in women. And if you look at just over the last three years since this discussion has been going on, there went from one case report to 11 case reports of cancers associated with mesh, and so that's Dietz, Goldman, Kwon.

I'm forgetting the study out of Asia on urethral carcinoma, but there are a growing number of cancers being reported with polypropylene mesh, and that tells you about the toxicity and the chronic foreign body reaction that is associated with it.

Q. So we've seen an increase up to 11 case

reports in the literature --

A. Correct.

Q. -- in patients who have mesh and also have --

A. Pelvic cancer associated with that mesh --

Q. How do you --

A. -- mesh.

Q. -- make the link between the mesh to the cancer?

MS. HUTSON: Object to form.

BY THE WITNESS:

A. It's at the same site.

BY MS. STEELE:

Q. That's enough epidemiological link for you?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Okay. The epidemiological discussion has been going on for chronic foreign bodies leading to tumor genesis. That has been going on for years.

So foreign bodies and toxic substances can lead to cancer, okay? Think of

mesotheliomas and asbestos, all right? So we know that happens. Now we're starting to see -- because widespread use in the pelvis only started 20 years ago and the length of time is between 20 and 30 years which has been found in other studies for tumor genesis.

So now we're starting to see more and more case reports. Again, I saw a case very recently where, you know, Stage 2 vaginal dysplasia in a woman that had a normal vagina and then she ended up with an ulceration and erosion, and when I freshened up the edges, sent it off to pathology, it came back vaginal intraepithelial neoplasia which is precancerous changes.

BY MS. STEELE:

Q. Just so whenever you use the word "toxic" in your report or testimony, how do you define toxic?

A. Having a deleterious effect.

Q. Your report does not contain any opinions regarding polypropylene mesh procurement from China, correct?

A. No.

Q. It does not, right?
A. It does not.
Q. You're not offering any opinions regarding resin procured from China, correct?
A. I think there has been a lot of opinions offered about that, but I did not put that in this report.
Q. Have you been in contact with any news agencies regarding Boston Scientific's procurement of resins from China?
A. No.
Q. I assume you viewed some news programs?
A. I did not --
MS. HUTSON: You don't have to answer that.
BY THE WITNESS:
A. I didn't have to to know about the story.
BY MS. STEELE:
Q. Can you always feel contracted mesh on exam?
A. Yes. And by "you," you meant me?
Q. You.
A. Correct.

Q. Can trained urogynecologists always feel contracted mesh on exam?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Well, there are trained urogynecologists who I've seen opine that mesh does not contract when there is overwhelming data that mesh does contract. Some might say, Well, it only contracts to a little bit.

But if you understand that mesh -- if you don't think mesh contracts, obviously you're not going to be able to feel it, right?

BY MS. STEELE:

Q. Yeah.

A. Okay. So yes, trained pelvic floor surgeons will be able to feel contracted mesh. Now, it depends on -- they might describe it differently. They might just describe it as banded. They might describe it as taut, tense. I mean, there are a variety of different verbiages that describe the same thing.

Mesh should not be palpable. Mesh should not be banded. Mesh should not be tense.

Q. For a transobturator sling, even if it

was implanted a month ago and hasn't undergone significant contraction, you can still feel the sling?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. You -- it should be -- if the true process of fat and blood vessels growing through the pores took place, it should be indistinguishable from the surrounding connective tissue. That was the idea. That's the bill of goods we were sold. That does not happen.

So starting very soon after implantation, once you move from the acute inflammatory response to the chronic inflammatory response to the chronic foreign body response, you get granulomas surrounding the individual fibers. That then coalesces and you get scar plating.

Now, can I borrow a sheet of paper?

MS. HUTSON: Will this work?

THE WITNESS: Yes.

BY THE WITNESS:

A. So it's been said that the mesh does

not contract because it doesn't have contractile fibers, right? It's the external forces that cause it to contract. The paper didn't have any -- doesn't have contractile forces. The external forces of my hand caused it to contract, but look at it now. It's contracted.

So what it looks like when you go in to take it out -- and I have described this in numerous case-specific depositions -- it goes in 1 to 1.1 centimeters. You take it out, it's 0.5 centimeters. That's contracted, and yes, you can feel that because it's scar plated, too.

BY MS. STEELE:

Q. So you would expect a finding of fibrotic bridging or excessive scarring for a mesh that's been implanted for a number of years?

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. I said scar plating. Now, excessive scarring, yes, you can have that too because you have this -- you know, particularly for POP mesh, you have a wide area of mesh that's going to undergo scarring.

BY MS. STEELE:

Q. And I believe you testified, and correct me if I'm wrong, that you want to not be able to feel the area of mesh with the tissue ingrowth, have it feel different than the tissue adjacent to the mesh; is that right?

A. Correct.

Q. But if the tissue around the mesh is weakened and was no longer doing its function of supporting the organs, wouldn't you want to be able to feel the mesh because it's a stronger tissue?

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. Well, now you're talking about form and function, okay? So it should be -- you can't feel the paraurethral ligaments that are supporting the urethra. You can't feel the endopelvic fascia that's supporting the bladder, the apex of the vagina or the posterior vaginal wall.

Now, that theory about yes, weakened connective tissue or separation of the arcus tendineum with the pelvis creating prolapse or

the loss of the pubourethral ligament, great theories. But no, you should not feel the mesh unless it is -- because it should move with the vagina, okay? If it doesn't move with the vagina, it's scar plated because of chronic foreign body reaction. It's going to contract, it's going to degrade, it's going to deform, it's going to rope and curl.

There is plenty of ultrasound studies. There are at least half a dozen studies documenting roping, curling, deformation of midurethral slings. We know that happens much more frequently with POP mesh. Even early TVM studies described an 18 to 20 percent mesh shrinkage and contraction rate.

So we know that it occurs. So it will -- if it -- if you had normal tissue ingrowth, you should be able to push it and it will move. But when you get scarification, it becomes fixed. It's also not supposed to be under tension, and tension is what makes it much more palpable. The only reason why it has increased the tension is because it contracted.

///

BY MS. STEELE:

Q. On exam after an anterior colporrhaphy, can you feel the scar from the anterior incision?

MS. HUTSON: Objection.

BY THE WITNESS:

A. It would be a very thin line. You might see where the scar is, but for the rest of the vaginal tissue, no, just a very thin line where you made your initial incision.

BY MS. STEELE:

Q. Now, turn to page 34, and looking at the first paragraph regarding Boston Scientific's experience with the Protegen.

A. Yes.

Q. And the Protegen was on the market for approximately three years before it was recalled; is that right?

A. Correct.

Q. And Boston Scientific's polypropylene midurethral slings have been on the market for over 15 years; is that right?

A. The first Advantage sling appeared 2002, 2003, yes.

Q. So within three years Boston Scientific, the medical community recognized that there was an issue with the Protegen sling, right?

A. Correct.

Q. And Boston Scientific acted and took the Protegen off the market, right?

A. Correct.

Q. No organization -- strike that. None of the societies or organizations in the United States for members of the urology, urogynecology or gynecology field has stated Boston Scientific's polypropylene midurethral slings should be taken off the market, right?

A. In the United States, yes. We've already discussed other places around the world.

Q. The FDA has not instructed Boston Scientific to remove its polypropylene midurethral slings from the market, correct?

A. At this time, no.

Q. And that's after 15 years on the market, right?

A. Correct.

Q. I want to turn to page 36 and I want to

talk about the last sentence of the first paragraph that starts with, "As of 2015."

A. Yes.

Q. And I think that there is similar -- that sentence is repeated in a few other locations throughout your report regarding Boston Scientific sponsoring studies?

A. Yes.

Q. How do you define "sponsored"?

A. That the -- it's not an investigator-initiated study or an investigator-sponsored study where the investigator goes to Boston Scientific and says, Hey, I'd like to do a study. Can I have some money?

It would be one that Boston Scientific would initiate, control, and carry out.

Q. So as of 2015 Boston Scientific had not sponsored a completed clinical trial other than the registry that you discuss; is that correct?

A. And the other studies that I talked about for Advantage, Obtryx, Pinnacle and Uphold.

Q. Boston Scientific has funded studies

regarding all of its polypropylene mesh products, correct?

A. Correct, as I describe in my report.

Q. Is a Boston Scientific-sponsored study reliable?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. If it's well done.

BY MS. STEELE:

Q. Is it biased because Boston Scientific sponsored it?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. If the sponsorship is disclosed, then the reader can determine for themselves if there is bias. If they have a significant editorial process on how the data is presented, then it will be biased and that needs to be described.

Is, you know, are -- what is the process of putting the data out? Is there some data that's being obfuscated? Is there some data that's being downplayed? I mean, we know that the vast majority of doctors read the abstract. Then a little bit less frequently

they read the abstract and the conclusion. And most doctors, unlike myself, don't read the whole paper.

So if you bury the lead in the body of the paper, you don't put it in the abstract, most doctors aren't going to see that. So a good paper will give all the information in the abstract knowing that that's what most doctors are going to read.

BY MS. STEELE:

Q. And you've been critical of studies in the past because Boston Scientific funded the studies, correct?

MS. HUTSON: Objection; form.

BY THE WITNESS:

A. Critical? I'm critical of the Costa studies of the registry and I describe that in my report, what is critical about those. I'm critical of the fact that studies are only presented as abstracts and some of them aren't even presented as abstracts -- they're just used as promotional material by Boston Scientific -- because the degree of editorial vigor is not the same for getting an abstract accepted and

presented and therefore published as a full-bodied study in a peer-reviewed journal.

So those are some of the reasons I'm critical, but I have described in my report what I'm critical of.

BY MS. STEELE:

Q. Are you critical of the 2015 Ross article involving Obtryx and Advantage?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. No. Again, I described that -- that's a good prospective randomized controlled trial with long-term five-year data that's not good.

BY MS. STEELE:

Q. And Boston Scientific funded that study, right?

A. Yes.

Q. Boston Scientific is currently sponsoring a mesh versus non-mesh study for pelvic organ prolapse, right?

A. The 522 study, correct.

Q. And Boston Scientific is also currently sponsoring a biologic versus no graft --

A. Correct.

Q. -- study, correct?

A. Correct.

Q. On page 37 the first paragraph details some information from a deposition of Janice Connor in 2015; is that right?

A. Correct.

Q. Did you independently search out these studies or articles?

A. Well, I know the Obtryx studies because we discussed that in West Virginia. I know the Advantage and the Lynx studies because we have described them in previous depositions and at trial last year. I know the Solyx studies because of the trial.

I -- as you probably know, I was an expert in the Flores case that settled right before it was going to go to trial, and that involved Uphold, Pinnacle, and I think Solyx. So for that I did an independent review of the literature.

As you probably know, I was supposed to do a de bene esse two or three months ago that got cancelled the day before because the patient underwent another surgery. That was on

Advantage Fit, but the thought was to do every -- all the other products.

So I did another review of the literature to make sure that I had everything for that. So for this I had already done all the reviews. But it goes to show, I bet there is some stuff that I can't find. And again, that's the problem with saying that doctors out there in the community who aren't preparing for trials and depositions and de bene esses and trying to find every piece of literature so that I can sit there and say, Yes, I looked at everything, and I still can't find everything.

That shows you that doctors don't know everything about these products. So you can't say that doctors have all the literature available and all they have to do is go out and look at the literature like as in the Instructions For Use, because most of the literature doctors can't find.

Q. So the Directions For Use contain a summary of every article that has ever been published on the device?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. No. It should contain the frequency, severity, treatability, and permanency.

BY MS. STEELE:

Q. I want to look at -- it states that, "Although randomized controlled trials represent the gold standard of clinical testing, BSC did not test the Advantage, Advantage Fit, Lynx, Obtryx, Prefyx, and Solyx products in RCTs, nor does any data from RCTs on the products otherwise exist in the medical or scientific literature."

Did I read that correctly?

A. Yes. We talked about the Ross study.

Q. So that sentence is incorrect?

A. We talked about the Ross study.

Q. And that was published in 2015?

A. Correct, and that's Advantage Obtryx.

Q. And your report was submitted in 2018, right?

A. Correct.

Q. And you don't have I believe -- you don't discuss the data presented in the long-term Ross study in your report, correct?

MS. HUTSON: Object to the form.
BY THE WITNESS:
A. No, because I've testified about it and we're talking about it now.
BY MS. STEELE:
Q. Well, I think as of the trial in Delaware last fall, you weren't aware of the long-term Ross study during that trial?
MS. HUTSON: Object to the form.
BY THE WITNESS:
A. I had it. That trial was the day before my wife had a hysterectomy for what we were worried about were precancerous changes. So obviously you're catching me on a much better day.
BY MS. STEELE:
Q. And the next paragraph starts with the sentence, "By contrast, other manufacturers of midurethral slings rely on hundreds of published studies, articles and trials to establish the effectiveness of the products. In my experience, it is exceedingly unusual to have such a limited body of medical and scientific literature to support the safety and

effectiveness of a permanently implantable medical device."

A. Correct.

Q. And you've testified that for all those manufacturers who are marketing midurethral slings, no matter how much literature is available on those slings, all of those slings are defective, right?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Well, the majority of the other manufacturers or the studies on other manufacturers are short term with small numbers, so even the meta-analysis have said that the quality of literature is moderate at best and that the number -- there are only prospective randomized controlled trials out to five years.

There is some ten-year cohort studies, but most of those rely on phone interviews to get the data on patients. And the Nielsen study -- I've testified about this -- is a very flawed study.

BY MS. STEELE:

Q. So even with the hundreds of published

studies, articles and trials, and you have your criticisms or limitations for each of those, for all of the other manufacturers of midurethral slings, you've testified or you hold the opinion that those slings are defective, correct?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Polypropylene is an inappropriate material to be used as a midurethral sling or a pelvic organ prolapse device to treat stress urinary incontinence or pelvic organ prolapse for the reasons I have described in my report.

BY MS. STEELE:

Q. If you turn to page 41, regarding the Uphold you state in the middle of the first full paragraph that, "For the Uphold, only four full-length, peer-reviewed articles on the Uphold existed in the medical literature as of 2015," right?

A. Yes.

Q. Have you done any literature search for any other full-length, peer-reviewed articles on Uphold since 2015?

A. There is the Altman Uphold Lite study

that came out 2016, the Gutman study that came out in 2017.

Q. Are you familiar with the Letouzey study that involved Uphold?

A. Yes.

Q. So if -- there is actually five full-length published studies that include data on the Uphold products, right?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. We would have to pull those out because I think the Letouzey is a combination of Pinnacle and Uphold so it's not pure data. What I'm talking about is pure. Just like the Gynemesh PS versus Polyform mesh, there was a mixture of Uphold and Pinnacle. So, you know, if you're mixing products, it's not a pure study.

BY MS. STEELE:

Q. And in your report you don't lay out any of the specific data regarding Uphold, correct?

MS. HUTSON: Object to form.

///

BY THE WITNESS:

A. Correct. It's all in the studies.

BY MS. STEELE:

Q. And in your footnotes you identify the four as Larouche, Jirschele, Rivaux and Vu?

A. Yes.

Q. And I think you have a criticism of Vu that there was inadequate disclosure?

A. Correct.

Q. Do you have criticisms of Larouche, Jirschele and Rivaux?

A. I don't specifically recall the conflict of interest. To be able to completely and accurately answer that question, I would need to have the study.

MS. STEELE: Can we take a quick break?

MS. HUTSON: Sure.

THE VIDEOGRAPHER: We are off the record at 12:04 p.m.

(Recess had.)

THE VIDEOGRAPHER: We are back on the record at 12:22 p.m.

BY MS. STEELE:

Q. After the implantable Boston Scientific

polypropylene mesh, how soon after does a scar plate form?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. I've been asked that at previous depositions and trials, and I'll stand by my prior statements.

BY MS. STEELE:

Q. And if that testimony was specific to a different device than the Boston Scientific mesh, would that correlate to the Boston Scientific mesh as well?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Yes.

BY MS. STEELE:

Q. Does shrinkage and contracture begin immediately?

A. Shrinkage and contracture starts when the chronic foreign body reaction starts, because what happens is you get fibrosis around the individual fibers. That fibrosis touches, it then creates a scar over the top of it. So the chronic foreign body reaction usually starts

anywhere from seven to ten days after implantation.

Q. And can that shrinkage and contracture cause symptoms immediately --

A. Immediately --

Q. -- once it begins?

MS. HUTSON: Object to form.

BY THE WITNESS:

A. Well, yes.

BY MS. STEELE:

Q. Is it your opinion that shrinkage and contracture of the polypropylene mesh causes pelvic floor muscle spasm or can cause pelvic floor muscle spasm?

A. Yes.

Q. When a patient comes into your office with pelvic floor muscle spasm, what are the other potential causes for pelvic floor muscle spasm?

MS. HUTSON: Object to form.

BY THE WITNESS:

A. Trauma, overuse, psychological dysfunction.

///

BY MS. STEELE:

Q. Any others?

A. There are probably more but they would fall into the category of trauma or overuse.

Q. And for trauma, can you explain what you mean by trauma?

A. Childbirth, surgical trauma, an accident.

Q. Does accident include such as a car accident?

A. If there is a pelvic fracture, yes.

Q. Overuse of the pelvic floor muscles, what circumstances constitute overuse?

A. Well, someone that -- the pelvic floor acts as a stabilizer for the upper and lower body, so if there is any kind of asymmetry, it's going to put stress on the pelvic floor muscles.

Q. So anything that would make you use one side of your pelvic floor more than the other?

A. That could be one of the overuse injuries, yes.

Q. And does that include -- overuse cannot be just someone who's on their feet all day moving a lot?

MS. HUTSON: Object to the form.
BY THE WITNESS:
A. There would be specific activities, not just from standing all day.
BY MS. STEELE:
Q. What are some of those certain activities?
A. Activities that cause your pelvis to stabilize.
Q. Such as standing, squatting, sitting?
A. No. More like sports activities, but someone that, you know, stood during activities would, you know -- I would not exclude that. That would not be outside the realm of possibilities.
Q. Can chronic untreated urinary tract infection cause pelvic floor muscle spasm?
A. Unlikely. Chronic cystitis could.
Q. Can any pelvic surgery fall into the category of trauma and cause or contribute to pelvic floor muscle spasm?
MS. HUTSON: Object to the form.
BY THE WITNESS:
A. If retractors are used and specifically

injure one of the pelvic floor muscles, yes. Just in and of itself, no.

BY MS. STEELE:

Q. Do you have any other trial settings on your calendar?

A. No. I have depositions that I can't talk about, but there you go talking about it.

Q. I think we can all assume that you'll be giving more depositions in the near future.

As far as lightweight mesh --

A. And by "lightweight" we're defining that as less than 35 grams per meter squared?

Q. Yes, so less than 35, and I believe Boston Scientific's Uphold Lite mesh falls into that category.

A. Yes, it does. It's around 30 grams per meter squared.

Q. You do not implant the Boston Scientific Uphold Lite mesh, correct?

A. Correct.

Q. Is it your opinion that the Boston Scientific Uphold Lite is not defective?

MS. HUTSON: Object to the form.

///

BY THE WITNESS:

A. I don't have any opinions about the Uphold Lite. I was not asked to provide opinions about the Uphold Lite and, therefore, I don't have opinions about the Uphold Lite because I was not asked to have opinions.

BY MS. STEELE:

Q. Would a Boston Scientific midurethral sling comprised of 30 grams per meter squared mesh be defective?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. As I stated before, the -- when Shepherd looked at all the lightweight meshes and found Ultrapro to be the least stiff, and because it has a dissolvable Monocryl component, I have testified that it leaves the lowest fingerprint of polypropylene.

So even though polypropylene is an inadequate or a -- what's the term that I use -- inappropriate material to be placed in the pelvis, with Ultrapro you have a lower amount and might be below the level that would cause significant complications.

So as an example, there are poisons in just about everything, but it is below that minimal level that is toxic, meaning causing injury. So that even though it does contain poisons, it's not toxic. And for the information that I have on Ultrapro, in general it is not toxic, as I've stated in prior depositions.

BY MS. STEELE:

Q. Do you have any intention of incorporating Ultrapro into your treatment of patients in the future?

A. No.

Q. Ultrapro, once you implant it, ultimately it's 28 grams per meter squared; is that correct?

A. Correct.

Q. So Boston Scientific's light mesh is approximately two grams per meter squared heavier than Ultrapro?

A. Correct, but it is stiffer, and I would direct you to the Shepherd study on mesh stiffness.

Q. Are you offering an opinion regarding

blue mesh versus clear mesh?

A. There are opinions in my report regarding blue mesh, that blue mesh enables you to find the demarcation point easier, though not easily. It's easier to find blue mesh than it is to find clear mesh when you're trying to do a removal procedure.

Q. Is that the limits of your opinions regarding blue mesh?

A. Correct. People have looked at -- I think it's cyanoethylene which is the dye that makes the mesh blue. I don't have any opinion about its toxicity, but there is another additive that goes into blue polypropylene.

Q. And you've not conducted any testing to determine the toxicity of Boston Scientific's polypropylene mesh, correct?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. The blue mesh or the clear mesh?

BY MS. STEELE:

Q. Either mesh.

MS. HUTSON: Form.

///

BY THE WITNESS:

A. The toxicity directly, no. Research, yes.

BY MS. STEELE:

Q. And your research is the articles that we've discussed?

A. Correct.

Q. And do you look at the path reports -- strike that. When you remove mesh, do you send it for a pathology review?

A. Yes.

Q. And do you review the pathology reports once the pathologist performs his examination?

A. Yes, which is how I found out that my recent patient had vaginal intraepithelial neoplasia.

Q. And do you recall what device that patient had?

A. A TVT obturator.

Q. Have you reviewed pathology reports from Boston Scientific mesh that you have explanted that showed toxicity?

MS. HUTSON: Object to the form.

///

BY THE WITNESS:

A. I cannot specifically recall all of the path reports from all of the mesh that I've removed that has been looked at.

BY MS. STEELE:

Q. Do you recall any pathology report for Boston Scientific mesh that you removed that indicated there was precancerous or cancerous cells present?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Not that I specifically recall.

BY MS. STEELE:

Q. Do you agree that just because a surgery has risks does not mean that that surgery is unreasonable?

A. I agree with that.

Q. Do you agree that just because there are risks does not make a medical device defective?

A. Correct.

Q. And do you agree that just because there are risks, that does not make a medical device unreasonable for use?

A. Correct.

MS. STEELE: Do you have any questions?

MS. HUTSON: I do not. I'll reserve.

MS. STEELE: Let me take one last glance. We may be done.

THE WITNESS: Ms. Hutson has to rush to the airport. And by "rush" I mean crawl.

MS. HUTSON: Hobble. I will hobble.

BY MS. STEELE:

Q. So the Pinnacle and the Uphold, besides the use of polypropylene mesh and that it's placed transvaginally, are there any other specific criticisms of those two devices that you have?

MS. HUTSON: Object to the form.

BY THE WITNESS:

A. Aside from what's in my report and what we discussed in this deposition, no.

MS. STEELE: No further questions.

MS. HUTSON: Okay.

THE VIDEOGRAPHER: We are off the record at 12:38 p.m. This concludes the videotaped deposition of Bruce Rosenzweig, M.D.

FURTHER DEPONENT SAITH NOT.

CERTIFICATE OF CERTIFIED SHORTHAND REPORTER

I, MARIANNE NEE, a Certified Shorthand Reporter of the State of Illinois, C.S.R. No. 084-002341, do hereby certify:

That previous to the commencement of the examination of the witness, the witness was duly sworn to testify the whole truth concerning the matters herein;

That the foregoing deposition transcript was reported stenographically by me and thereafter reduced to typewriting under my personal direction;

That the reading and signing of said deposition was reserved by counsel for the respective parties and the witness;

That the foregoing constitutes a true record of the proceedings had and testimony taken, to the best of my abilities;

That I am not a relative, employee, attorney or counsel, nor a relative or employee of such attorney or counsel for any of the parties hereto, nor interested directly or indirectly in the outcome of this action.

SIGNED THIS 3rd DAY of SEPTEMBER, 2018.

_____

Marianne Nee, CSR, RPR, RDR
Illinois Certified Shorthand Reporter No. 084-002341.

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E R R A T A

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ACKNOWLEDGMENT OF DEPONENT

I, BRUCE A. ROSENZWEIG, M.D., do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

BRUCE A. ROSENZWEIG, M.D. DATE

Subscribed and sworn
to before me this_____
day of_____20____.
My commission expires:_____

_____
Notary Public